Lantheus Announces First Patient Dosed in SPARROW Phase 2/3 Registrational Trial in Prostate Cancer

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Study advances development of Lantheus' investigational GRPR-targeted PET imaging program for prostate cancer

BEDFORD, Mass., Sept. 28, 2026 (GLOBE NEWSWIRE) -- Lantheus Holdings, Inc. ("Lantheus" or the "Company") (NASDAQ: LNTH), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, today announced that the first patient has been dosed in SPARROW NCT07831824, a Phase 2/3 registrational trial evaluating LNTH-2401 (^{68}Ga-DOTA-RM2). LNTH-2401 is an investigational gallium-68-labeled positron emission tomography (PET) imaging agent that targets the gastrin-releasing peptide receptor (GRPR), a biomarker that is highly expressed in many prostate cancers.

SPARROW is an open-label, non-randomized, multicenter Phase 2/3 study that includes an initial Phase 2 dose optimization period followed by a Phase 3 diagnostic performance period. The Phase 3 co-primary endpoints are sensitivity and specificity of LNTH-2401 PET/CT imaging compared with histopathology. The Phase 3 portion of the trial is expected to enroll approximately 400 participants and will evaluate diagnostic performance, safety and tolerability.

“Accurate characterization of disease remains critically important in prostate cancer, particularly as treatment decisions become increasingly personalized,” said Harshad R. Kulkarni, MD, Chief Medical Advisor at BAMF Health and a principal investigator in the SPARROW study. “We are pleased to have dosed the first patient at BAMF Health, where our integrated molecular imaging, radiopharmacy and clinical trials infrastructure supports the evaluation of emerging radiopharmaceutical technologies. GRPR represents a promising and biologically distinct target in prostate cancer, and SPARROW will help define the role GRPR-targeted PET may play in disease detection and characterization.”

GRPR is highly expressed in many primary prostate cancers and has a biologic expression pattern distinct from PSMA. Emerging research suggests GRPR-targeted imaging may provide additional insight in certain tumors that are not optimally characterized using PSMA-directed approaches alone.[1]

“Dosing the first patient in SPARROW represents a significant step forward for our pipeline and underscores our commitment to advancing innovative radiopharmaceuticals across the prostate cancer care continuum,” said Ludger Dinkelborg, Head of Research and Development at Lantheus. “As the leader in prostate cancer PSMA PET imaging, LNTH-2401 has the potential to expand our understanding of prostate cancer biology through a complementary imaging target. This program reflects our broader strategy to build a focused pipeline of differentiated radiodiagnostics that may support more informed clinical decision-making.”

About SPARROW

SPARROW is an open-label, non-randomized, multicenter Phase 2/3 clinical trial evaluating investigational 68Ga-LNTH-2401 PET/CT imaging in prostate cancer. The study consists of a Phase 2 dose optimization period followed by a Phase 3 diagnostic performance period.

During Phase 2, up to 12 imaging-evaluable participants with newly diagnosed or biochemically recurrent prostate cancer will receive 68Ga-LNTH-2401 PET/CT imaging to determine the optimal administered activity and imaging time window. Phase 2 will also assess biodistribution, radiation dosimetry, image quality, safety and tolerability. Data from participants with GRPR-positive lesions are expected to support selection of the administered activity and imaging time window for Phase 3.

During Phase 3, approximately 400 participants with newly diagnosed prostate cancer who are at least high risk or have suspected metastatic disease and are eligible for radical prostatectomy with pelvic lymph node dissection will undergo 68Ga-LNTH-2401 PET/CT imaging using the optimized imaging parameters selected during Phase 2.

The Phase 3 co-primary endpoints are participant-level sensitivity and specificity of 68Ga-LNTH-2401 PET/CT imaging compared with histopathology. Secondary diagnostic performance assessments include positive predictive value (PPV), negative predictive value (NPV), regional detection performance, comparative summaries versus conventional imaging and/or PSMA PET imaging where applicable, and assessment of inter-reader and intra-reader agreement. Safety and tolerability will also be evaluated.

About Lantheus

Lantheus is the leading radiopharmaceutical-focused company, delivering life-changing science to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. Headquartered in Massachusetts with offices in New Jersey, Canada, Germany, Sweden, Switzerland and the United Kingdom, Lantheus has been providing radiopharmaceutical solutions for more than 70 years. For more information, visit www.lantheus.com.

Safe Harbor for Forward-Looking and Cautionary Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are subject to risks and uncertainties and are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by their use of terms such as “can,” “continue,” “could,” “future,” “potential,” “will” and other similar terms. Such forward-looking statements are based upon current plans, estimates and expectations that are subject to risks and uncertainties that could cause actual results to materially differ from those described in the forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Readers are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date hereof. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law. Risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements include (i) the timing and potential outcomes of clinical studies, including SPARROW, evaluating the use of LNTH-2401 for the detection and characterization of prostate cancer; (ii) our ability to develop LNTH-2401 as a PET imaging agent; and (iii) the risks and uncertainties discussed in our filings with the Securities and Exchange Commission (including those described in the Risk Factors section in our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q).

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[1]Gastrin-Releasing Peptide Receptor (GRPR) as a Novel Biomarker and Therapeutic Target in Prostate Cancer. National Library of Medicine. Published March 5, 2024. Accessed September 10, 2025. https://pmc.ncbi.nlm.nih.gov/articles/PMC10916925/